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00:00:00,080 --> 00:00:10,080

Welcome to the ISPE podcast, shaping the future of pharma, where ISPE supports you on your journey, fueling innovation, sharing insights, thought

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00:00:10,080 --> 00:00:14,240

leadership, and empowering a global community to reimagine what's possible.

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00:00:15,414 --> 00:00:20,135

Welcome to the ISPE podcast, shaping the future of pharma.

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00:00:20,535 --> 00:00:22,375

I'm Bob Chew, your host.

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00:00:22,454 --> 00:00:32,609

And today, we have another episode where we'll be sharing the latest insights and thought leadership on manufacturing, technology, supply chains and regulatory

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00:00:32,609 --> 00:00:36,049

trends impacting the pharmaceutical industry.

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00:00:36,609 --> 00:00:43,754

You will hear directly from the innovators, experts and professionals driving progress and shaping the future.

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00:00:44,234 --> 00:00:45,914

Thank you again for joining us.

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00:00:46,155 --> 00:00:48,715

And now let's dive into this episode.

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00:00:49,354 --> 00:00:58,679

Our topic today is the use of applied AI in pharma manufacturing in general and workforce readiness in particular.

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00:00:59,159 --> 00:01:09,239

To share more about this topic, I would like to welcome Susan Szathmary and Richard Jaenisch, both of Open Biopharma Research and Training Institute.

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00:01:09,799 --> 00:01:13,224
Welcome to this podcast, shaping the future of pharma.

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00:01:13,784 --> 00:01:14,825
Thank you for having us.

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00:01:14,825 --> 00:01:16,105
Thank you for having us.

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00:01:17,465 --> 00:01:22,745
First, please tell me about Open Biopharma Research and Training Institute.

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00:01:22,745 --> 00:01:26,905
How did it get started, and what is its scope of services today?

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00:01:28,740 --> 00:01:32,819
Open Biopharma started in in 2020.

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00:01:33,299 --> 00:01:34,740
It's a brand new institute.

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00:01:34,740 --> 00:01:42,100
We have about 45,000 square feet of facility with 6,000 square foot of open clean room space.

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00:01:42,605 --> 00:01:52,924
And the idea was to provide training in on project in on the job training, focusing on human error reduction

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00:01:53,325 --> 00:01:54,844
and focusing on The U.

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00:01:54,844 --> 00:01:55,084
S.

23
00:01:55,084 --> 00:01:55,564
Technologies.

24
00:01:56,020 --> 00:02:02,819
So students and employees looking for new job or riskier or upskill, they can find training on The U.

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00:02:02,819 --> 00:02:03,140

S.

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00:02:03,140 --> 00:02:03,780

Technologies.

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00:02:03,780 --> 00:02:07,459

So this is how we incorporated AI also into our training.

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00:02:07,459 --> 00:02:10,099

All of our faculty are all coming from the industry.

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00:02:10,099 --> 00:02:12,675

So they worked at CDMO's pharma companies.

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00:02:13,155 --> 00:02:17,955

And we also have a great mentor group who are working in pharma.

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00:02:18,275 --> 00:02:23,635

So one of our major focus is advanced technologies too and advanced therapies.

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00:02:23,635 --> 00:02:28,050

So we focus on cell therapy and cell and gene therapy also.

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00:02:28,689 --> 00:02:32,689

And that's basically the core of our things.

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00:02:32,689 --> 00:02:35,810

It's more like a residency type of training.

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00:02:35,810 --> 00:02:42,370

We're not the school, but more like the next step, like a residency to get somebody ready for critical manufacturing steps.

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00:02:42,504 --> 00:02:45,465

We like to do that bridge between, you know, academia and industries.

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00:02:45,465 --> 00:02:46,985

And there's often a gap between them.

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00:02:46,985 --> 00:02:56,585

We wanna make sure that, you know, there are folks who are coming out of the coming out of these academic institutions who are right ready to work, ready to and and not just ready to work, like, ready to

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00:02:56,585 --> 00:02:57,705

work at a at a certain level.

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00:02:58,349 --> 00:03:06,110

And so, you know, one of the goals of our of our nonprofit, you because Open Biopharma Research and Training Institute is a nonprofit training institute.

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00:03:06,430 --> 00:03:10,030

And we also have, you know, we have a we have a core lab services.

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00:03:10,030 --> 00:03:17,405

We have our, you know, our polypractical production space, and we have our our training services that we we offer, and we also host as a venue as well.

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00:03:17,405 --> 00:03:26,365

So we have often a host, leading training services and training come training from different organizations who are have industry ready training.

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00:03:26,580 --> 00:03:34,740

And though we often bring do we often work deals with them to have a a channel for all of our, apprentices and interns to be able to access that training.

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00:03:34,740 --> 00:03:38,180

So this way, then when they come out, they're that's how we say when they're industry ready.

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00:03:38,180 --> 00:03:47,215

They're they're able to do all of these other things and actually try out these different elements, work on the core lab services, and really get a real well rounded, level of experience to understand where

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00:03:47,215 --> 00:03:48,735

they best fit.

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00:03:48,735 --> 00:03:52,895

Because oftentimes, it can be difficult when you're in college trying to figure out exactly what you wanna do.

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00:03:52,895 --> 00:03:56,334

And then that never really matches with whatever industry is about to do because it always changes.

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00:03:56,400 --> 00:03:59,919

You know, two years, five years, that's difficult for these things to work.

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00:03:59,919 --> 00:04:02,080

So that's Open Biopharma in a nutshell.

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00:04:02,719 --> 00:04:08,000

And, yeah, we're we're happy to be here, and it's a great it's a great organization.

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00:04:08,000 --> 00:04:08,479

Thank you.

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00:04:08,479 --> 00:04:15,974

So I've visited your facilities, which are located, what, in Carlsbad, North Of San Diego.

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00:04:16,454 --> 00:04:27,220

Maybe tell our audience a little bit more about what you've got in the labs and in the development or production spaces?

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So we have clean room space, and we're focused on having equipment like single use bioreactors, chromatography systems.

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00:04:37,584 --> 00:04:47,584

So the very basic ones, everybody can train on on the basic elements, can train on how to connect them, how to gone, how to do environment monitoring in a

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00:04:48,029 --> 00:04:49,470

in a GMP setting.

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00:04:49,470 --> 00:05:00,875

And then we also have a lot of quality control type of equipment in our facilities, so flow cytometers, the absorptors, sequencer, PCR

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00:05:00,875 --> 00:05:03,754

machines, you know, chromatography.

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00:05:03,754 --> 00:05:11,754

And then we're also working on new technologies, for example, for cell and gene therapy, how we can liquid biopsy, their culture Yeah.

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00:05:12,089 --> 00:05:21,290

During production and get more information what's going in the cells so we can characterize EVs that coming out of cells and live cells and work on those.

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00:05:21,290 --> 00:05:27,685

And the students are basically exposed to all the technologies, and we have a rotation.

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00:05:27,685 --> 00:05:34,165

Make sure they 100% pipette, 100% can work in a septic environment.

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00:05:34,564 --> 00:05:38,805

And then they familiar with upstream, downstream and the quality control technologies.

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00:05:39,300 --> 00:05:39,699

Yes.

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00:05:39,699 --> 00:05:42,019

And we have a number of different locations we do that.

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00:05:42,019 --> 00:05:45,300

We have a training we have a training lab specifically dedicated to this space.

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00:05:45,379 --> 00:05:49,939

We have our upstairs spaces, which are more, you know, your basic training rooms, more for our venue operations.

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00:05:49,939 --> 00:05:57,074

But we also have a dry lab and wet lab upstairs as well for folks who wanna be able to have kind of a mixed mode experience depending upon their training.

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00:05:58,275 --> 00:05:59,475

Well, that sounds Sorry.

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00:06:00,275 --> 00:06:02,915

That sounds very comprehensive.

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00:06:04,899 --> 00:06:12,500

But tell tell me how your use of AI, is improving how you are training your students.

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00:06:13,699 --> 00:06:23,384

So when it comes to AI, we started working with it very kind of oh, and not really early on per se because, you know, AI has been around since nineteen forties, technically speaking.

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00:06:23,384 --> 00:06:23,865

Right?

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00:06:24,345 --> 00:06:30,985

So but what we're talking about when we use AI is, generally speaking, we're using, we started using generative AI.

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00:06:31,305 --> 00:06:40,580

So what that means in our case is that in 2000 in 2023, all of our we started with our apprentices, and we went, okay.

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00:06:40,580 --> 00:06:46,420

How do we make sure to give them the readiness they need to work in the in the in the future for the future workforce.

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00:06:46,420 --> 00:06:46,900

Right?

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00:06:46,900 --> 00:06:50,154

And so what we did was we started identifying.

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00:06:50,154 --> 00:06:57,995

We saw there was a there was a paper from the federal from the Fed that explained what the strong suits and weeks and weaknesses of are these are these tools.

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00:06:57,995 --> 00:06:58,634

And we said, okay.

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00:06:58,634 --> 00:07:01,675

Well, it seems we're weak research is a bit of a a weak point.

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00:07:01,675 --> 00:07:01,914

Why?

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00:07:02,310 --> 00:07:09,430

And we knew that research is a very critical element, these students are learning, and these apprentices are learning how to really conduct appropriate research.

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00:07:09,589 --> 00:07:11,430

And so we wanted to really test that.

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00:07:11,430 --> 00:07:21,245

So we started doing what's called a parallel project where everything that they would do, they would have the they would train what, what we'll call an AI assistant to do at the same time.

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00:07:21,245 --> 00:07:24,845

And so they would iterate this forth back and forth, and they've been doing this for years at this point.

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00:07:24,845 --> 00:07:27,004

So every cohort that comes on does the same thing.

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00:07:27,379 --> 00:07:32,019

And so everything that they're doing, when they do it, they do it in parallel with the actual AI assistant.

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00:07:32,099 --> 00:07:33,220

They create the assistant.

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00:07:33,220 --> 00:07:34,339

They build the elements in there.

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00:07:34,339 --> 00:07:45,264

And so that this way, what they're doing, creates a little bit of that that tacit record kind of gets a little bit more under better understood because it also means that when, inevitably,

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00:07:45,504 --> 00:07:53,985

the apprentice or intern leaves because we are an institute that takes an apprentices and and and interns on in six month, year, two year, they differ.

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00:07:54,144 --> 00:07:56,625

And so a project, you know, might suffer from a gap.

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00:07:56,625 --> 00:07:59,839

And so this allows the next person to kind of pop up and go, oh, look.

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00:07:59,839 --> 00:08:00,560

Here's the assistant.

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00:08:00,560 --> 00:08:02,240

Let's let's help them kinda carry along.

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00:08:02,240 --> 00:08:03,919

It ends up kind of carrying these gaps forward.

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00:08:03,919 --> 00:08:09,839

And so it ended up being a really useful tool to kind of carry along this tribal knowledge that normally kind of can get a little bit lost along the way.

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00:08:10,319 --> 00:08:18,295

It also meant that in this way, they were also testing their own critical thinking skills because that was one of the elements that I found out early on is that it was bad.

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00:08:18,694 --> 00:08:28,879

Early generative AI in in in 2023, was, you know, maybe at best, had hit about a 10% ratio in terms of the success rate to actually

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00:08:28,879 --> 00:08:31,759

get the link and the name and all the rest of materials right.

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00:08:32,000 --> 00:08:33,679
Now maybe it's about 40%.

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00:08:33,679 --> 00:08:34,399
It's getting better.

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00:08:34,399 --> 00:08:35,840
And this is off the shelf tool.

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00:08:35,840 --> 00:08:38,320
So when you really hone something, and that's what they learned.

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00:08:38,320 --> 00:08:40,480
When they really honed something, they managed to make it better.

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00:08:40,865 --> 00:08:42,625
But we're not just using it there.

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00:08:42,784 --> 00:08:48,625
So that's what we started working with it there to make sure that all of our staff have a really good understanding as well as all of our apprentices.

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00:08:48,625 --> 00:08:57,550
Anyone who really walks through our doors, we wanna make sure that they're a little bit better off, you know, understanding what the AI landscape looks like and how to integrate it into their workflows.

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00:08:57,710 --> 00:09:05,470
When we think about the other enhancements that we we're solely putting into play is we have a lot of sensors and cameras, a lot of data that we've been collecting.

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00:09:05,470 --> 00:09:09,309
We're trying to find new ways of leveraging that, and we'll get into that a little bit later on.

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00:09:09,309 --> 00:09:19,465
But where it happens with these with these apprentices is that they get to see actively, you know, how this change occurs over time with their assistant

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00:09:19,465 --> 00:09:22,345

and see how their assistant is kind of, like, almost a partner to them.

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00:09:24,059 --> 00:09:25,740

Well, that sounds very interesting.

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00:09:26,299 --> 00:09:33,259

So besides working with your students, how are you using AI today for your day to day operations?

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00:09:35,125 --> 00:09:41,845

So one of the things that we've been doing is that we have been, kind of upgrading our sensors and upgrading our data acquisition.

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00:09:42,085 --> 00:09:52,110

So in order to properly install really generative AI, AI, predictive AI, whatever AI you wanna put in there, you really need to have good, not only good sorting

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00:09:52,110 --> 00:10:01,070

of data in terms of data governance, you need to have a plan as to what sensors you're plugging in, how you want them to work into your workflow, how do these things make sense, because if you don't have

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00:10:01,070 --> 00:10:01,950

that collection that's there.

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00:10:01,950 --> 00:10:04,670

So that's really where a large portion of where the steps are.

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00:10:04,754 --> 00:10:14,835

We're also while we're doing this, we are finishing up the pilot of our of our initial element here, which is a, an integration where

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00:10:14,835 --> 00:10:21,669

we have a a program that has generative AI elements into it, but it isn't fully generative AI.

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00:10:21,669 --> 00:10:24,470

It's a combination of a few different types of AI.

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00:10:25,350 --> 00:10:31,029

My my brother is the architect here for this, so I have to kinda lean on him for the specifics of the engineering behind it.

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00:10:31,429 --> 00:10:33,190

I'm just the guy who communicates the elements.

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00:10:33,190 --> 00:10:42,365

So when it comes to it, what it ends up doing is it allows us to access our inventory, access our systems much cleaner, much easier, and importantly, in a way that's accessible.

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00:10:42,524 --> 00:10:51,090

So one of the biggest changes that we have regarding our the tools that we have built for our own internal management, so inventory and other elements.

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00:10:51,090 --> 00:10:53,410

It's almost like an ERP system, but it's not quite there.

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00:10:53,730 --> 00:10:57,649

The idea here is that we we look at it and we say, how do these things connect?

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00:10:57,649 --> 00:10:59,009

How does this work together?

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00:10:59,570 --> 00:11:06,324

And how do we how do we make sure that we're best leveraging all of our materials and all of our time?

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00:11:06,324 --> 00:11:11,365

It's kind of like a little bit of a resource management, a little bit of better resource tools because, you know, we're a nonprofit.

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00:11:11,365 --> 00:11:16,084

We have to leverage with what we can and what we have, and we're we're scrappy at the end of the day.

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00:11:17,320 --> 00:11:22,120

We'll scrapping a 45,000 square foot facility, as much as that happens.

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00:11:22,519 --> 00:11:32,675

But, the the main thing about this, though, is that this allows us to because of the generative AI element integrated into it and because we've worked with so

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00:11:32,675 --> 00:11:42,434

many of these, not just apprentices, but also our our, our various, employees, myself, I am a a person with a few different disabilities if my glasses don't give me away.

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00:11:43,394 --> 00:11:49,970

And and what that means is that it can be difficult for me to read certain types of screens.

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00:11:50,210 --> 00:11:53,009

Like, for instance, I have visual dyslexia.

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00:11:53,009 --> 00:11:55,730

When I look at a screen, I I kinda mix up letters and words a little bit.

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00:11:55,730 --> 00:11:57,889

Actually, I mix up concepts, which is a little more complex.

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00:11:57,889 --> 00:12:04,934

But, anyway, point is that what ends up happening is that when I look at a screen, it becomes difficult for me to particularly read certain types of fonts.

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00:12:04,934 --> 00:12:13,095

And so what we've done is we've actually had a whole bunch of assistive, components that actually completely change the interface so that this way it adapts to the user.

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00:12:13,095 --> 00:12:17,570

And the user can change however they need to, and it doesn't matter because the whole system works together.

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00:12:17,649 --> 00:12:21,809

So if somebody has, you know, vision problems like I do, I can easily adjust it.

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00:12:21,809 --> 00:12:23,490

I can put it on a high contrast mode.

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00:12:23,490 --> 00:12:26,930

I can put it on all these different modes so that this way it doesn't matter if I'm color blind.

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00:12:26,930 --> 00:12:30,370

It doesn't matter if I have any sort of visual component that's that's challenged there.

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00:12:30,585 --> 00:12:32,024

It's also screen reader friendly.

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00:12:32,024 --> 00:12:36,904

So this way, we can have folks who maybe have even more visual problems than I do working in there.

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00:12:36,904 --> 00:12:47,029

And so the benefit of this tool is that it's really, really inclusive in terms of how it's able to personalize for all these individuals who may have different needs or different interests because

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00:12:47,029 --> 00:12:49,190

maybe you don't use the tools in the same way.

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00:12:49,190 --> 00:12:51,589

And so the system is a bit more adaptive.

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00:12:51,750 --> 00:12:59,909

It actually is able to kind of adapt to the user, which is really important because every user really has different concerns about what matters to them.

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00:13:01,654 --> 00:13:08,774

So, you mentioned that this system is pulling data from a number of sensors and other sources.

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00:13:09,254 --> 00:13:19,759

Does it do kind of old fashioned statistical process control, charts, and that sort of thing, from a purely statistical analysis

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00:13:19,759 --> 00:13:20,639

point of view?

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00:13:20,720 --> 00:13:26,720

And can the user, basically kinda create their own views of data?

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00:13:27,985 --> 00:13:28,465
Yeah.

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00:13:28,465 --> 00:13:30,705
So it on the back end, yes.

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00:13:30,705 --> 00:13:34,144
It's it's it's it's that it's big charts and tables.

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00:13:34,225 --> 00:13:38,065
But in the front end, the user can completely customize whatever that appearance says.

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00:13:38,065 --> 00:13:44,809
And that goes for all of our tools, including probably one of our most essential tools, which is DAISOPs.

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00:13:44,889 --> 00:13:47,049
It's a learning tool that happens daily.

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00:13:47,289 --> 00:13:54,649
And and with that tool, they're able to keep up to date with whatever new thing that is going on in our in our building.

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00:13:55,524 --> 00:13:58,004
We'll have our trainings, we'll have that element in there.

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00:13:58,245 --> 00:14:05,205
And there, again, that adaptive approach in terms of how the actual appearance works for that user is really front and center.

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00:14:05,205 --> 00:14:08,165
Pretty very quickly, you can click on it and adjust it as you need to.

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00:14:09,820 --> 00:14:14,220
Any other ways that, AI is being used by your clients?

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00:14:16,779 --> 00:14:23,419
So with AI being used to our clients, I can't explicitly say what some of our clients are doing behind the doors.

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00:14:23,419 --> 00:14:29,554

But but with us, what happens, we have a number of different ways we utilize AI with our clients.

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00:14:29,634 --> 00:14:39,899

One is that anyone doing a project with us, all of our since all of our, all of our operators are trained in use of AI, they can better understand

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00:14:39,899 --> 00:14:43,339

where in the workflow AI needs to be integrated.

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00:14:43,339 --> 00:14:46,059

And the thing is that's, think, one of the more difficult components.

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00:14:46,059 --> 00:14:49,019

When I have discussions with a lot of folks, they really don't know where AI fits.

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00:14:49,019 --> 00:14:53,259

Most of the time, they're like, oh, I know we have this great generative AI tool, but, like, what does it do?

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00:14:53,259 --> 00:14:54,059

Where do I put this?

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00:14:54,514 --> 00:15:01,154

And so what we've done is we've really given the operators a really good understanding as to how the tools can work.

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00:15:01,154 --> 00:15:03,875

This way, when they see a project, they go, I know where to put AI.

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00:15:03,875 --> 00:15:04,835

Let's put it here.

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00:15:04,914 --> 00:15:05,634

Let's put it here.

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00:15:05,634 --> 00:15:06,195

Let's put it here.

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00:15:06,440 --> 00:15:11,959

This will help reduce the overall burden on our workflow, help make sure that we can get it done in a lot less time.

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00:15:11,959 --> 00:15:13,799

And I think that's an important component.

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00:15:13,799 --> 00:15:21,720

It's really a combination of our critical thinking skills from the operator as well as understanding where to put the AI tools along the workflow for our clients.

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00:15:21,965 --> 00:15:32,125

And then also for any clients who come in and do a training on our site, we offer both, DISOPs, which is a competency assessment tool,

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00:15:32,605 --> 00:15:42,709

to any training that happens on our site, as well as our survey tool, Compare, which essentially is a qualitative, survey that doesn't really

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00:15:42,709 --> 00:15:52,309

concern itself so much as the idea is, like, a normal survey where it asks similar questions, but instead actually looks to to analyze the answers because that's really what matters in a qualitative

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00:15:52,309 --> 00:15:52,629

approach.

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00:15:52,944 --> 00:15:59,105

And so those tools are ones we offer to any client who comes on-site, who wants to do a training, who wants to do a project.

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00:15:59,105 --> 00:16:06,464

Because the DISOPs also allow for something called, you know you know, something that's really familiar to a lot of us in in management, which is risk management.

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00:16:06,929 --> 00:16:16,450

Because the benefit of DISOPs is that you assess the competency of the individual as they go, you assess the competency as they learn, and you get a better understanding as to where their strengths and

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00:16:16,450 --> 00:16:24,075

weaknesses are in a way that normal, you know, read and understand SOPs just probably doesn't capture.

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00:16:25,675 --> 00:16:30,315

I'm not saying it's not the industry standard, but I'm just saying maybe it's not the best.

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00:16:31,035 --> 00:16:32,554

Maybe there are better approaches.

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00:16:32,554 --> 00:16:37,195

I mean we were ready to we learned to cheat on multiple choice tests.

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00:16:37,670 --> 00:16:43,029

So this is non cheating because the answers, there is no good answer or bad answer.

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00:16:43,029 --> 00:16:47,509

It statistically compares it to the expert answer.

200

00:16:47,590 --> 00:16:58,245

You actually can assess the real skills and also see how you can position, for example, an employee in a work environment

201

00:16:58,564 --> 00:17:09,640

to handle the risk and who are to be the one who are going to be able to handle the risk, who are the ones who can be promoted based on their knowledge more

202

00:17:09,640 --> 00:17:14,759

into supervisory position rather than basing it on other elements.

203

00:17:14,759 --> 00:17:25,015

And also, a bunch of us, our family have that we have perfect training records and yet there are human errors in a production.

204

00:17:25,975 --> 00:17:31,815

We can read out the sources before actually the losses occur due to this human error.

205

00:17:31,815 --> 00:17:38,169

So this is where we see a big advantage for the ISOP that it gives you a transparent tool.

206

00:17:38,329 --> 00:17:42,809

It also potentially gives you a transparent tool to go for interviews.

207

00:17:42,809 --> 00:17:48,650

People are switching jobs, and this could be a portable record that they can bring with themselves.

208

00:17:48,650 --> 00:17:58,825

So instead of lying on the resume that I did this or I did that, and I've just seen it from far away, people can actually the new employers can actually see what they did

209

00:17:58,825 --> 00:18:02,184

and how competent they are in certain processes.

210

00:18:02,184 --> 00:18:09,730

So and ultimately, this reduces the human errors, which for some of the pharma companies can cost hundreds of millions a year.

211

00:18:09,809 --> 00:18:10,130

Yes.

212

00:18:10,130 --> 00:18:20,345

And I mean, maybe not lying, but maybe some people inflate maybe what they did or something and understanding their competency directly in a traceable, transparent record

213

00:18:20,345 --> 00:18:21,704

is just a lot better.

214

00:18:22,105 --> 00:18:28,984

It is a much more portable digital certificate than, you know, you're gonna find from some other digital service, you know, system.

215

00:18:28,984 --> 00:18:30,825

We we wanted to make it useful to us.

216

00:18:31,039 --> 00:18:31,359

Mhmm.

217

00:18:31,359 --> 00:18:32,960

So we wanted to make it useful to the industry.

218

00:18:32,960 --> 00:18:36,960

We wanted to to make it so that this way, you know, people would benefit from it.

219

00:18:36,960 --> 00:18:45,119

Because, you know, we see the challenge with all of our with all of our trainees, with all of our with all of our new folks, you know, because we work a lot with colleges in terms of getting hired.

220

00:18:45,119 --> 00:18:51,325

Because as you mentioned, it can be very difficult, you know, finding the right person for the role, figuring out what they're good at, what they're not.

221

00:18:51,404 --> 00:18:56,845

These are all things that can be, you know, can be can help, this tool can help kind of delineate.

222

00:18:56,845 --> 00:19:01,440

And so and, also, DISOP stands for digitally interactive standard operating procedures.

223

00:19:01,440 --> 00:19:03,200

I probably should have mentioned that earlier.

224

00:19:03,599 --> 00:19:07,359

But it is not actually the sense of that your SOPs are digitally interactive.

225

00:19:07,359 --> 00:19:11,599

It's that this is a set of SOPs that are digitally interactive for the learning process.

226

00:19:11,599 --> 00:19:14,880

They are separate and not part of the DXP process, I should say.

227

00:19:16,644 --> 00:19:20,404

So to go off on a tangent for a second Sure.

228

00:19:20,404 --> 00:19:27,285

Was was it University of San Diego where the undergrads were a little bit deficient in math?

229

00:19:28,650 --> 00:19:39,130

And do you see this kind of an AI application, being kind of a, objective measure

230

00:19:39,130 --> 00:19:40,970

of student capability?

231

00:19:41,764 --> 00:19:50,244

And do you think it will get broader acceptance and recognition as kind of a certificate?

232

00:19:50,884 --> 00:20:01,229

I hope so because this is a transparent record and a lot of pipeline, workforce pipeline that's coming down, they can be on the spectrum.

233

00:20:01,629 --> 00:20:07,949

They don't necessarily very well, but they actually could work very well in a GMP environment.

234

00:20:08,269 --> 00:20:13,734

And this could be a transparent record for them that they're not screened out in HR.

235

00:20:13,734 --> 00:20:18,454

But I think it should replace eventually the multiple choice questions.

236

00:20:18,454 --> 00:20:26,989

So right now, hiring was based on the reputation of the institution, but doesn't necessarily mean that everybody who graduates from there are really great.

237

00:20:27,390 --> 00:20:30,750

Now there is how well you pass multiple choice questions.

238

00:20:30,750 --> 00:20:37,950

And I think by the time you get to graduate level, you already know how to cheat on those or how to beat the a little bit.

239

00:20:38,075 --> 00:20:42,234

Well, you understand well, I mean, under reading a test is a whole skill in itself.

240

00:20:42,234 --> 00:20:44,714

And, like so I I was very I was very good at it.

241

00:20:44,714 --> 00:20:50,234

And so I could I could take a test, but in a subject I've never learned and get a b on it when never having taken the class.

242

00:20:50,394 --> 00:20:52,234

Just understanding the the test itself.

243

00:20:52,234 --> 00:20:59,160

And that's not a good, you know, approach of learning it, and that's also a component of it too because it may it may have been SDSU.

244

00:20:59,160 --> 00:20:59,720

I'm not certain.

245

00:20:59,720 --> 00:21:06,680

But the the the challenge is that some subjects can be a little bit more difficult to understand that translation.

246

00:21:06,680 --> 00:21:07,000

Right?

247

00:21:07,000 --> 00:21:10,025

Because they so they got an a.

248

00:21:10,025 --> 00:21:11,144

So they got a b.

249

00:21:11,144 --> 00:21:14,424

What is an a and a b worth in this environment?

250

00:21:14,664 --> 00:21:24,750

You know, what are these grades worth in this environment when you have all of these you have both grade inflation, you have all of these components have kind of entered the picture that

251

00:21:24,750 --> 00:21:26,990

that make it very difficult to discern these things.

252

00:21:26,990 --> 00:21:28,750

And a transcript doesn't tell you that.

253

00:21:28,750 --> 00:21:30,429

A syllabus doesn't tell you that.

254

00:21:30,429 --> 00:21:37,069

A syllabus tells you what they conceptually could have learned, and it and a and a transcript tells you that they got the grade they got.

255

00:21:37,069 --> 00:21:39,984

It does not give you a really good transparent record.

256

00:21:39,984 --> 00:21:42,625

And the goal of this document is to say, hey.

257

00:21:42,785 --> 00:21:47,265

This is where this person has strengths, weaknesses, and this is where they've shown a lot of growth.

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00:21:47,345 --> 00:21:51,025

This is where, you know, they might be this might they might have a little more room to grow here.

259

00:21:51,509 --> 00:21:59,750

And the the goal of this is is to really make that, you know, portability, make it strong, and make it so that this way you can better understand your teams.

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00:21:59,750 --> 00:22:01,830

It makes everyone be able to work better together.

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00:22:01,830 --> 00:22:08,454

If we understand where someone is, it's a lot easier to communicate with them what their needs are and how they're able to work with the team.

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00:22:08,454 --> 00:22:14,454

And specifically in pharma, we have a risk based management for our whole operation.

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00:22:15,015 --> 00:22:25,230

So I think this could address the risk part you can put the right people who potentially in a more risky situation in your process versus putting

264

00:22:25,230 --> 00:22:33,815

somebody who shown less familiarity with the process yet into a different position.

265

00:22:33,815 --> 00:22:38,855

And I think that could actually mean millions for a pharma company, putting the right people.

266

00:22:38,855 --> 00:22:47,950

So a lot of times in real operation, you find out if somebody really knows what they're supposed to know when they made a mistake and say, oops, it's expensive.

267

00:22:47,950 --> 00:22:58,109

So this way, you could know ahead of the time if they're of doing it or likely to work well, and you can start to position your employees

268

00:22:58,109 --> 00:22:58,909

based on risk.

269

00:23:00,284 --> 00:23:09,404

And I think that's for us as a nonprofit, a big advantage to see who assess who knows what.

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00:23:09,325 --> 00:23:11,565

I think it's translate to pharma too.

271

00:23:11,640 --> 00:23:12,599

We gotta be lean.

272

00:23:12,599 --> 00:23:13,320

We gotta be lean.

273

00:23:13,320 --> 00:23:13,559

Right?

274

00:23:13,559 --> 00:23:18,839

And, you know, if if we have the lean practices, we hope for other folks to be able to learn from from our space.

275

00:23:18,839 --> 00:23:19,559

That's what we do.

276

00:23:19,559 --> 00:23:19,799

Right?

277

00:23:19,799 --> 00:23:20,839

We we test it.

278

00:23:20,839 --> 00:23:22,359

We we we're the sandbox.

279

00:23:22,519 --> 00:23:29,575

We're a space for you to play around with, try out these new tactics, these new equipment, these new these new, implementations, whatever you wanna try out.

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00:23:29,575 --> 00:23:32,214

We want you to try it out here, see how it works.

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00:23:32,214 --> 00:23:39,575

That's why we try to produce this information to make it ready for folks so that folks in the industry can find a way to integrate it into their own systems and say, hey.

282

00:23:40,309 --> 00:23:41,990

This is how we wanna improve.

283

00:23:42,069 --> 00:23:43,990

We wanna reduce the cost of pharmaceuticals.

284

00:23:43,990 --> 00:23:46,869

You know, my my bill to insurance total was \$6,000,000.

285

00:23:46,950 --> 00:23:48,710

You know, I'm a I'm a liver transplant patient.

286

00:23:48,710 --> 00:23:55,349

I was cured of hepatitis c, you know, almost thirty years after I was, you know, because I was born with it.

287

00:23:56,204 --> 00:23:59,724

And so, you know, to me, that reducing that cost is big.

288

00:23:59,724 --> 00:24:05,484

And all the all of our efforts, all of our things here are really in that vein of trying to reduce that cost.

289

00:24:05,484 --> 00:24:08,365

And we think industry adoption is definitely an important component.

290

00:24:08,365 --> 00:24:08,924

Yes.

291

00:24:08,899 --> 00:24:19,299

And so I think battery and workforce that has 100% competency on key technologies have improved on actually every step in the manufacturing

292

00:24:19,299 --> 00:24:20,659

of what they need to do.

293

00:24:20,659 --> 00:24:28,704

Is it like measuring liquid, measuring solid, transferring liquid, transferring solid, working in our septic environment.

294

00:24:28,704 --> 00:24:35,505

So we basically broke down the basic steps, make sure they have the competency, and we assess it with the DISOP.

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00:24:36,210 --> 00:24:46,450

And I think, provide reduction of cost for pharma, having less human error, which related losses, which is obviously

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00:24:46,450 --> 00:24:53,494

built into the cost of the drug actually could be a big savings for everybody all around.

297

00:24:53,494 --> 00:24:57,894

And these are expenses from these losses that shouldn't occur.

298

00:24:58,695 --> 00:25:01,894

For some of the large pharma, it's hundreds of millions a year.

299

00:25:04,480 --> 00:25:13,039

Does your operation create standard deviations just like pharma manufacturing?

300
00:25:13,599 --> 00:25:14,239
Mhmm.

301
00:25:14,559 --> 00:25:15,279
Yes.

302
00:25:15,599 --> 00:25:17,119
So we work with yeah.

303
00:25:17,119 --> 00:25:20,984
We basically have a GMP system.

304
00:25:21,065 --> 00:25:24,184
Actually, all students build a system.

305
00:25:24,184 --> 00:25:34,410
So build, you know, GMP quality system, and they operate the system so they understand that in and out of how this works, which rarely is a possibility

306
00:25:34,410 --> 00:25:41,850
for that because in pharma, you get and see a fraction of the whole GMP quality system.

307
00:25:41,850 --> 00:25:52,224
And with us, it's we want to see we want to make sure that our graduates actually see the whole quality system and understand how the different

308
00:25:52,224 --> 00:25:53,664
wheels work together.

309
00:25:53,825 --> 00:25:55,825
So yes, so that's part of it.

310
00:25:55,984 --> 00:26:06,059
So where I was going with this is many times a deviation gets resolved, quote, unquote, by saying, well,

311
00:26:06,059 --> 00:26:11,339
it was operator error, and we retrained the operator.

312
00:26:11,339 --> 00:26:11,980
Yes.

313
00:26:12,299 --> 00:26:12,779
Okay?

314
00:26:12,779 --> 00:26:23,055
Now so the training was inadequate to begin with, and we're gonna retrain the operator on a training system that was inadequate

315
00:26:23,055 --> 00:26:23,934
to begin with.

316
00:26:23,934 --> 00:26:24,734
Exactly.

317
00:26:24,815 --> 00:26:27,134
That's the logic that I see here.

318
00:26:27,134 --> 00:26:27,934
But Yeah.

319
00:26:27,934 --> 00:26:35,569
Would your AI be able to kind of cry foul and say, wait a minute.

320
00:26:35,890 --> 00:26:46,134
The human error was either, okay, the individual really screwed up or the training was not good enough or

321
00:26:46,134 --> 00:26:55,015
the SOP is confusing or there's some other root cause in the manufacturing system that needs to be addressed.

322
00:26:55,015 --> 00:26:55,414
Yeah.

323
00:26:55,414 --> 00:26:58,934
Do you see AI getting us to that place?

324
00:26:59,369 --> 00:27:00,410
Oh, I mean, absolutely.

325

00:27:00,410 --> 00:27:02,169

That's exactly before.

326

00:27:02,170 --> 00:27:11,690

So so one of the things one of the first projects, you know, that because on the side, my brother and I, you know, we we we do consulting for generative AI.

327

00:27:12,025 --> 00:27:16,744

And one of the things we did was one of the first projects we did was on deviations, was around deviations.

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00:27:17,304 --> 00:27:20,825

And the thing is, you know, this is something that we see commonly now.

329

00:27:21,065 --> 00:27:29,579

All of the big players all have AI built into looking at their deviations because it is just it's it's a great way to summarize a lot of elements and reduce a lot of the the the hours.

330

00:27:29,579 --> 00:27:32,139

It's a pretty low hanging fruit, generally.

331

00:27:32,299 --> 00:27:37,579

But the thing is that part that you touched on was is not something I hear a lot about.

332

00:27:38,044 --> 00:27:39,085

They always hear about, hey.

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00:27:39,085 --> 00:27:41,884

I'm moving it, but they're like, ah, but we don't wanna solve the problem, though.

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00:27:41,884 --> 00:27:45,964

That that part is a bit absent, which is unfortunate because I think it's such a missed opportunity.

335

00:27:45,964 --> 00:27:47,244

And I think you're right.

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00:27:47,244 --> 00:27:56,210

I and I think this is one of the areas where, you know, we're going to see our when our deviations come out come into play, and we see that element that says, hey.

337

00:27:56,210 --> 00:27:57,489

This is a human error.

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00:27:57,730 --> 00:28:02,049

We happen to have the training record that's very transparent, that's very that's very traceable test.

339

00:28:02,049 --> 00:28:02,529

Oh, look.

340

00:28:02,529 --> 00:28:07,490

Looks like they're we see right here that they're missing this specific pipetting skill.

341

00:28:07,545 --> 00:28:12,345

What we see now why this did not work, well, because they're not doing very well in this.

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00:28:12,345 --> 00:28:18,265

Let's go back and retrain them on this specific area so we don't have to waste time with all the rest of this because this is the real weak point.

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00:28:18,585 --> 00:28:21,819

Focus on that, and then we'll probably see a lot better results.

344

00:28:21,819 --> 00:28:26,380

Now I say probably because we haven't instituted that yet, but we will see that happen in the future.

345

00:28:26,380 --> 00:28:27,419

I'm certain of it.

346

00:28:27,500 --> 00:28:28,059

Yeah.

347

00:28:28,299 --> 00:28:28,619

Yeah.

348

00:28:28,619 --> 00:28:35,335

I mean, using AI to write a deviation that, you know, okay.

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00:28:35,335 --> 00:28:37,974

That's kind of an efficiency tool.

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00:28:37,974 --> 00:28:38,454

Yeah.

351

00:28:38,534 --> 00:28:41,094

But AI is statistics.

352

00:28:41,095 --> 00:28:49,095

And using AI to statistically say, you really think it's it's retraining is gonna work?

353

00:28:49,095 --> 00:28:56,169

Well, my statistics tell me that, you have a ten percent chance of being successful with that approach.

354

00:28:56,490 --> 00:28:57,769

Do you think we'll get there?

355

00:28:57,930 --> 00:28:58,490

Yes.

356

00:28:58,490 --> 00:28:59,450

Oh, absolutely.

357

00:28:59,450 --> 00:29:02,650

That's that's kind of the goal to get there.

358

00:29:02,650 --> 00:29:08,265

But the other side of it, we also train our students focusing of the language.

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00:29:08,265 --> 00:29:10,585

So they actually have to write their SOPs.

360

00:29:11,065 --> 00:29:18,424

And we're looking at how things in an SOP could lead to human error and how we can eliminate that.

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00:29:18,820 --> 00:29:28,980

So we're training them also to how to write SOPs and without things like, for example, if you have a sentence that has two things in it, typically the second

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00:29:28,980 --> 00:29:39,265

part of the sentence where the error is going to happen because if you the SOP say, do this and then do that, the second part sometimes get where

363

00:29:39,265 --> 00:29:40,224

the error happens.

364

00:29:40,224 --> 00:29:47,825

So we basically write, train them how to write SOPs to avoid human errors and set it up properly.

365

00:29:48,470 --> 00:29:52,789

And then, so we're looking at that as a potential resource as well.

366

00:29:52,789 --> 00:30:02,914

And I think, yes, it's AI going to come in because AI helps us with that to sort out some of these basic elements that based on human behavior already

367

00:30:02,914 --> 00:30:11,394

shown in other industries that leads to human errors, like a nuclear power or space industries.

368

00:30:11,394 --> 00:30:11,875

Yes.

369

00:30:11,875 --> 00:30:19,519

And at the end of the day, AI can be integrated with SOPs very SOPs are kind of the language of a lot of generative AI kind of anyway.

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00:30:19,599 --> 00:30:25,279

If you really think about the if you break down how an LM works, I mean, you're talking about the tokens, each of the words.

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00:30:25,279 --> 00:30:25,519
Right?

372
00:30:25,519 --> 00:30:28,720
And words are things that modify words or what tokens are.

373
00:30:28,960 --> 00:30:38,875
And and so what that means in this instance is with an SOP, it's just a series of tokens that all interrelate, and you have the right vectors that associate with them, vectors being that they tie the things

374
00:30:38,875 --> 00:30:41,034
closest to one another and associated objects.

375
00:30:41,034 --> 00:30:46,990
The the idea here is that the SOP is actually a really good framework generally for an LLM to understand.

376
00:30:47,150 --> 00:30:52,589
An LLM being a large language model like like ChatGPT or any of those other tools, DeepSea.

377
00:30:52,589 --> 00:30:56,109
Any any of the tools, even if it's off or closed or open, doesn't matter.

378
00:30:56,190 --> 00:31:02,234
The idea here is that, you know, when we use a generative AI tool, which is an LLM, sorry for using all these language here.

379
00:31:02,234 --> 00:31:02,954
Don't worry.

380
00:31:02,954 --> 00:31:07,994
There'll be you can learn more with AI literacy stuff that we do with the AI COP.

381
00:31:08,474 --> 00:31:11,594
Just a plug for the ISP, AI COP for a second.

382
00:31:12,234 --> 00:31:13,514
You know, please do join us.

383

00:31:13,514 --> 00:31:14,794
We are working more with AI literacy.

384
00:31:14,794 --> 00:31:15,194
It's great.

385
00:31:16,490 --> 00:31:22,329
But the idea here being that with SOPs, they're a prime opportunity as well.

386
00:31:22,730 --> 00:31:29,529
And maybe the way they're designed, maybe whether they're structured, like you're saying that order isn't necessarily the best way, maybe there's a way to make that better.

387
00:31:29,845 --> 00:31:37,525
And one of the nice things about this is not only with, with these tools can you suddenly make sweeping changes to different SOPs.

388
00:31:37,605 --> 00:31:40,325
You can so, obviously, you're taking them out of your quality system.

389
00:31:40,325 --> 00:31:42,005
You're not gonna do this live in a real system.

390
00:31:42,005 --> 00:31:52,299
But, you know, in a in a in a in a in a more of a sandbox environment, you can really kind of, you know, tweak these SOPs to to protect them in a way that is you know, would take a long,

391
00:31:52,299 --> 00:31:54,859
long time without generative AI.

392
00:31:55,340 --> 00:32:00,779
You know, we've been experimenting with a few different ways to look at SOPs generally that are not part of that quality system.

393
00:32:00,974 --> 00:32:06,095
So this way, we can see them from a learning standpoint, and we're wondering how that will eventually translate.

394
00:32:06,335 --> 00:32:11,214

And, you know, we'll talk more about that probably near the end of the year once we've got a lot more data on that.

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00:32:11,615 --> 00:32:14,609

But, you know, for now, this is where we are.

396

00:32:14,609 --> 00:32:24,769

Reading these issues from a pharmaceutical process and looking at the training record, looking at what could lead

397

00:32:24,769 --> 00:32:31,134

to error in an SOP and potentially DCR the SOP and upgrade it to less human errors.

398

00:32:31,134 --> 00:32:34,014

Think AI is a great tool for that.

399

00:32:34,575 --> 00:32:37,375

So let me ask two related questions.

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00:32:37,375 --> 00:32:42,255

They both are around the subject of visual or visualization.

401

00:32:43,130 --> 00:32:50,809

One, are you looking at how to integrate video into an SOP?

402

00:32:51,210 --> 00:32:58,025

And two, are you using vision systems to assess operator competency?

403

00:32:59,865 --> 00:33:02,904

So vision is an interesting situation.

404

00:33:02,904 --> 00:33:10,664

So one thing that we've been attempting to do with sensors and camera is really understand how someone is meeting the SOP.

405

00:33:10,859 --> 00:33:18,859

And that's something that we've been kind of working on for a long time, I think it's gonna take a little while yet to really understand exactly how somebody someone is moving or is doing something and

406

00:33:18,859 --> 00:33:24,940

how that matches an SOP because of the way people are physically positioned, and there are many other factors involved in that.

407

00:33:24,940 --> 00:33:28,565

So that's why it's gonna take a little bit longer to better understand that element.

408

00:33:28,804 --> 00:33:38,325

But there are obvious other ones, like having a more more kind of digital SOP where it is it does, like you're saying, have a have video.

409

00:33:38,325 --> 00:33:41,524

Say, oh, well, this is something we don't do very often, but it's very critical.

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00:33:41,640 --> 00:33:51,880

Here's a video of an operator exactly going through with it and explaining step by step along with that the SOP already does, but reiterating it again and showing it as they are doing it right

411

00:33:51,880 --> 00:33:52,359

through there.

412

00:33:52,359 --> 00:34:00,894

And I think we've seen, we've worked with with groups doing, AR as well on that approach and saying how this works with AR, which is useful.

413

00:34:01,214 --> 00:34:08,255

However, the the challenge I think with, you know, with with VR and with AR is, again, the certain limitations of of the tool itself.

414

00:34:08,255 --> 00:34:08,494

Right?

415

00:34:08,494 --> 00:34:11,614

So with with VR, it's a matter of, like, I can't use VR.

416

00:34:11,614 --> 00:34:18,110

Like, I'm too my my my eyes are such that, you know, it is very difficult for me to be on VR for a time.

417

00:34:18,269 --> 00:34:21,150

And I have colleagues who get vertigo very quickly on them as well.

418

00:34:21,150 --> 00:34:23,070

So it it it does have limitations.

419

00:34:23,389 --> 00:34:28,844

That being said, watching the video or seeing a video on an iPad while you're there in there and saying, okay.

420

00:34:28,844 --> 00:34:30,125

Well, this is what I need to do.

421

00:34:30,125 --> 00:34:31,164

I can see that.

422

00:34:31,164 --> 00:34:36,605

Or having a tool you can kinda show up over the iPad or the augmented reality situation, that's really amazing.

423

00:34:36,900 --> 00:34:38,179

Being able to kinda say, okay.

424

00:34:38,179 --> 00:34:42,579

Well, here's where my next steps are following that SOP along those ways.

425

00:34:42,659 --> 00:34:43,619

Phenomenal.

426

00:34:44,099 --> 00:34:54,235

Something that we definitely will look at once we have, you know, more operations going in our in our actual in in our clean rooms because at the end of the day, until that happens, we're

427

00:34:54,235 --> 00:34:55,195

not on that.

428

00:34:55,195 --> 00:34:57,275

We we can't produce data or check on it.

429

00:34:57,275 --> 00:35:04,315

But in terms of our training lab, where we are there, there, you know, it's we're mostly looking at how are their pipetting skills?

430

00:35:04,315 --> 00:35:05,594

How are they working under the hood?

431

00:35:05,869 --> 00:35:07,630

How are they working at the microscope?

432

00:35:07,630 --> 00:35:11,949

How are they how are they, you know, working in these more more traditional laboratory settings?

433

00:35:11,949 --> 00:35:13,150

So we look at it there.

434

00:35:13,550 --> 00:35:18,829

We're looking at both the video that's, being taken, and there they can kind of set up a a sample video.

435

00:35:18,829 --> 00:35:18,989

Yeah.

436

00:35:19,985 --> 00:35:20,864

So I think Alright.

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00:35:20,864 --> 00:35:30,945

Let's question the the videos could be distracted, but I think, you know, learning in the first place and have the training and the training completed so

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00:35:30,945 --> 00:35:32,625

they're competent with the SOP.

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00:35:32,625 --> 00:35:34,720

I think it's kind of the good way to go.

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00:35:34,720 --> 00:35:35,200

Yes.

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00:35:36,160 --> 00:35:44,320

So let's shift the focus a little bit to Open BioPharma and its commercial endeavors.

442

00:35:44,320 --> 00:35:45,599
How are you funded?

443
00:35:45,599 --> 00:35:48,079
Is it public, private or a mix?

444
00:35:49,144 --> 00:35:53,385
So it's a Open Biopharma is a 501C nonprofit.

445
00:35:53,385 --> 00:35:58,025
So partially, we are funded by participating in grants.

446
00:35:58,025 --> 00:36:01,945
So we have workforce development grants and other grants with partners.

447
00:36:01,945 --> 00:36:05,320
We partner with community colleges, universities.

448
00:36:05,559 --> 00:36:14,920
We partners also across the industry, with Texas, A and M and North Carolina, and they're applying for different workforce development grants.

449
00:36:14,920 --> 00:36:25,135
So all one of our core thing to make sure we develop the future workforce, and that workforce is going to reduce these human error elements and move

450
00:36:25,135 --> 00:36:29,934
some of the new technologies potentially faster into the pharma space.

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00:36:29,934 --> 00:36:31,135
So that's one of our source.

452
00:36:31,430 --> 00:36:35,910
We have other grant sources too, then we work as a training facility.

453
00:36:35,910 --> 00:36:39,750
So we have other companies come and train or we co train with them.

454
00:36:39,750 --> 00:36:42,630
We develop our own training program.

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00:36:43,190 --> 00:36:52,074

And then we also working since we had a hands on, you know, on the job training, we bring in projects from companies.

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00:36:52,074 --> 00:36:52,635

Mhmm.

457

00:36:52,795 --> 00:36:53,994

Project based learning is a big one.

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00:36:53,994 --> 00:36:57,675

Project based learning, and we bring in projects from from companies.

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00:36:57,755 --> 00:36:59,755

And they sponsor the training.

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00:37:00,170 --> 00:37:07,690

For example, we agreed that this six months, the one year project, they sponsor the training and we deliver.

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00:37:07,690 --> 00:37:13,849

And this is all for our students is they have capstone projects a lot of times.

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00:37:14,675 --> 00:37:17,795

And we accomplished actually pretty good.

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00:37:17,795 --> 00:37:26,994

So there are products that's going out of this process that students has developed and helping the cell and gene therapy industry soon.

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00:37:27,179 --> 00:37:27,739

Pretty big win.

465

00:37:27,739 --> 00:37:29,819

One market and it's a pretty big win.

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00:37:29,819 --> 00:37:41,105

And for them to have also an experience that they're developing product, we're also helping small companies to translate processes or process development into manufacturing and

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00:37:41,105 --> 00:37:43,264

try to fill that gap.

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00:37:43,264 --> 00:37:52,864

And this is the gap where CDMOs are not making money, but doing it the wrong way can cause the company their life or could cause their investment.

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00:37:52,864 --> 00:37:55,824

So we're trying to help us a nonprofit in this early space.

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00:37:56,380 --> 00:37:58,699

Too, and we're bringing in several projects.

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00:37:58,699 --> 00:38:00,460

And then we have industry partners.

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00:38:00,460 --> 00:38:06,139

We're working with an application data, sales force training and other application.

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00:38:06,139 --> 00:38:16,525

And then we started also series of conferences or mini symposia around CMC.

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00:38:16,525 --> 00:38:18,204

We found a great need for that.

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00:38:18,204 --> 00:38:23,484

We had the first CMC conference in December, and we had close to 100 participants.

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00:38:24,039 --> 00:38:29,880

And so the facility was packed actually, and we continue next one in April.

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00:38:29,880 --> 00:38:36,440

So we will continue the CMC because we see the need that this is where there's a huge gap.

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00:38:36,994 --> 00:38:37,554

Yeah.

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00:38:37,554 --> 00:38:39,315

And we also host.

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00:38:39,554 --> 00:38:48,594

So we so if anyone has any training that they wanna, you know, derisk and and move off their site, you know, obviously, we have the space for it both in the training lab and then the and then the CNC and

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00:38:48,594 --> 00:38:52,289

clean room spaces as well as our training, you know, room itself.

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00:38:52,289 --> 00:38:54,210

Like I said, upstairs, dry lab, wet lab.

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00:38:54,210 --> 00:38:55,890

We have a lot of different options up there.

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00:38:56,130 --> 00:38:58,210

So we host trainings from our from organizations.

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00:38:58,210 --> 00:38:59,969

That's that's another source of revenue.

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00:38:59,969 --> 00:39:01,730

We also put on our own trainings.

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00:39:01,730 --> 00:39:09,324

We actually have a have an AI workshop series that we've launched, and we're gonna be having some different AI workshops throughout the year.

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00:39:09,405 --> 00:39:11,324

We'll be having a number of number of ones.

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00:39:11,324 --> 00:39:12,925

We have a few codeveloped ones.

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00:39:12,925 --> 00:39:16,844

We've designed them for specific agencies and then kind of expanded them.

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00:39:16,844 --> 00:39:18,045
We have one that we designed for CIRM.

492
00:39:18,860 --> 00:39:24,140
That's specifically a cell workshop therapy that we give off that we that we we do every year.

493
00:39:24,300 --> 00:39:33,664
And we'll be actually preparing it for industry as well because we've in conversation, it seems like a lot of folks would really like to better understand what cell and gene therapy, like, is if you're

494
00:39:33,664 --> 00:39:40,304
if you're in the sales or if you're in vision development or in that space where you just kinda entered into it and you're like, well, I'm from other areas of biopharma or life sciences, but I don't know

495
00:39:40,304 --> 00:39:41,664
what cell and gene therapy is.

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00:39:41,664 --> 00:39:51,710
And this way, can get a they can get an immersive two week workshop where they get to do all the fun stuff with with some different I forget what cells they work with because I I

497
00:39:51,710 --> 00:39:52,349
don't work with it too many.

498
00:39:52,590 --> 00:39:54,349
Work with iPSCs.

499
00:39:54,349 --> 00:39:56,670
We work with Amazon cameras, stem cells.

500
00:39:56,670 --> 00:39:58,349
We work with CAR T cells.

501
00:39:58,349 --> 00:39:59,390
So we have T cells.

502
00:39:59,390 --> 00:40:00,590
We have microphages.

503

00:40:00,590 --> 00:40:01,954
We have all kinds of cells.

504

00:40:01,954 --> 00:40:02,114
Yeah.

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00:40:02,114 --> 00:40:04,195
So it's a lot of fun to work around and better understand.

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00:40:04,195 --> 00:40:04,515
Yeah.

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00:40:04,515 --> 00:40:07,394
Those are less fun, I have to say, generally speaking.

508

00:40:07,394 --> 00:40:09,954
More fun in a laboratory setting when it's not around you.

509

00:40:10,594 --> 00:40:14,594
But, yeah, so it we have a very diverse set of different ways of funding.

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00:40:14,594 --> 00:40:16,355
We also obviously accept donations.

511

00:40:16,440 --> 00:40:17,000
You know?

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00:40:17,000 --> 00:40:25,880
So if you ever see our if you ever see on our on our on our on our Zephy
page where we're we have a training on there, there is a little donation
button you can add at the bottom as well.

513

00:40:26,679 --> 00:40:32,344
So as a nonprofit, what inspires you to do this work?

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00:40:33,784 --> 00:40:36,664
I mean, I came from medicine.

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00:40:36,744 --> 00:40:40,985
So I'm originally trained as an MD as a pediatric surgeon.

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00:40:41,224 --> 00:40:44,344

And I had kids with cancer, and my box was empty.

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00:40:44,559 --> 00:40:48,719

So I started out first on the research side, got my PhD.

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00:40:48,960 --> 00:40:52,960

And then I realized that research is a bunch of really great ideas.

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00:40:52,960 --> 00:40:56,239

But until it's not manufactured, it's nothing for a physician.

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00:40:56,985 --> 00:41:07,465

So I actually, throughout my career, I worked in different aspects of this, worked on building vaccine facility, registration of

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00:41:07,704 --> 00:41:16,719

medical device, overseeing as quality clinical studies and appreciated where the gaps are.

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00:41:16,719 --> 00:41:23,280

And as a nonprofit, we would like to be a community resource to solve some of these gaps and difficulties for the industry.

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00:41:23,765 --> 00:41:26,324

And we have the luxury of doing that.

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00:41:26,324 --> 00:41:33,925

So when companies are producing and they're under the gun to get things out, they, a lot of times, don't have the time to do this.

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00:41:34,405 --> 00:41:43,829

And we think that by providing the trained employees who already have the right thinking and the right skills, it can move into the industry.

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00:41:43,829 --> 00:41:54,085

And we feel that filling some of these gaps on the workforce side and also providing the opportunity for small companies to de risk their

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00:41:54,085 --> 00:41:59,525

CMC operation and be able to obtain financing.

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00:41:59,845 --> 00:42:06,805

These are great community resources and we're also going to move new technologies into medicine, have medicines for patients.

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00:42:06,929 --> 00:42:10,210

So these are the fun part that excites me.

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00:42:10,210 --> 00:42:20,050

And then see the young generation make a change because I think we our generation already have a routine of how we do things.

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00:42:20,050 --> 00:42:24,175

So I think to move the needle is gonna be the job for the young generation.

532

00:42:24,494 --> 00:42:27,215

And we want to make sure that we train them well.

533

00:42:27,295 --> 00:42:27,614

Yes.

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00:42:27,614 --> 00:42:37,750

And when when Susan came to you with this idea of what what Open Biopharma would be, you know, I at the time I had you know, ten years ago, I was very

535

00:42:38,710 --> 00:42:39,429

dying.

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00:42:40,070 --> 00:42:45,269

I was an end stage liver disease at that point for almost six years, maybe seven years about that point.

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00:42:45,589 --> 00:42:49,269

And, you know, I I was dying from hepatitis c, and I contracted at birth.

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00:42:49,269 --> 00:42:51,034

And I've been on five different treatments.

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00:42:51,034 --> 00:42:53,835

And I had been that that small percentage that it didn't work for.

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00:42:54,234 --> 00:42:56,714

And, you know, my bill to insurance total was massive.

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00:42:56,714 --> 00:43:03,674

You know, by the time I got my liver transplant and was eventually cured in 2017, you know, a bill to insurance total was \$6,000,000.

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00:43:04,059 --> 00:43:04,859

That's difficult.

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00:43:04,859 --> 00:43:06,219

Now my family didn't pay that.

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00:43:06,219 --> 00:43:14,940

My family paid about 350,000, maybe about \$450,000 out of pocket, but that's still a hefty amount of money over a life period.

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00:43:15,179 --> 00:43:17,659

And that's really difficult, you know, to bear.

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00:43:17,659 --> 00:43:24,885

It's difficult to to see, you know, how those things even my dog agrees with that, you know, if you could hear him barking in the background right now.

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00:43:24,885 --> 00:43:31,605

So the thing is that this was this was a this was a challenge, you know, for me personally.

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00:43:31,684 --> 00:43:40,239

And, you know, the fact that my life had been saved, you know, Because when I was diagnosed at 13 in '99, there was no treatment for there was no cure for hepatitis c.

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00:43:40,239 --> 00:43:41,680

Was a treatment, but it sucked.

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00:43:42,000 --> 00:43:43,119

It was it was a year long.

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00:43:43,119 --> 00:43:44,000

It was very rough.

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00:43:44,000 --> 00:43:54,224

And, you know, to have a curative treatment happen in your lifetime, to be cured of a terminal condition in your lifetime, to be saved by so many different processes,

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00:43:54,305 --> 00:43:57,425

and then to see all of the components within that were involved.

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00:43:57,425 --> 00:43:58,865

And it was so complex.

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00:43:58,945 --> 00:44:09,009

And, really, just I'm here by by luck, by chance, by, by by will, by by by the by by such a combination of forces that I think that that shouldn't have to

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00:44:09,009 --> 00:44:13,250

happen, you know, for everyone to be saved from such a circumstance.

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00:44:13,250 --> 00:44:23,835

And so I think that one of the things that really drives us here is making sure that more people have access to life saving and life and quality of life improving medications.

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00:44:24,235 --> 00:44:26,795

Because the thing is they exist out there.

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00:44:26,875 --> 00:44:30,635

There are amazing things that are being invented and created all the time.

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00:44:30,969 --> 00:44:35,610

And our industry has shown that you can improve and save so many lives.

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00:44:35,930 --> 00:44:44,969

And I think that it is just a matter of getting the right alignment of things to make those costs and make that accessibility really happen.

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00:44:45,324 --> 00:44:47,324

And I think that's really a lot of what we try to do here.

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00:44:47,324 --> 00:44:57,565

We try to make things so this way the industry can have the opportunity to align itself better, to be a bit more smooth operating in terms of, you know, getting from, you know, getting from school to

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00:44:57,565 --> 00:45:07,059

working, having that efficiency gain, having the the the access to knowledge of production because we are pretty secretive in in the pharmaceutical industry and trying to share secrets.

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00:45:07,059 --> 00:45:08,820

We don't we try not to do that very often.

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00:45:08,900 --> 00:45:10,579

It is what we're kind of known for.

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00:45:10,579 --> 00:45:11,300

We have a process.

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00:45:11,300 --> 00:45:11,780

You're like, no.

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00:45:11,780 --> 00:45:12,820

This is my process.

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00:45:12,820 --> 00:45:16,295

And, you know, that can be difficult for advancement.

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00:45:16,295 --> 00:45:26,295

And so we wanna be a space, a place for people to be able to sandbox and try those things, to try the new projects, to be innovative in a way that maybe, you know, helps save and improve some

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00:45:26,295 --> 00:45:27,094

lives in the future.

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00:45:27,349 --> 00:45:31,910

And we just wanna be a part of this amazing industry that helps save and improve lives.

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00:45:31,989 --> 00:45:34,949

I would like to add something really quickly.

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00:45:34,949 --> 00:45:38,630

So I, you know, I got the training as a as a surgeon.

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00:45:39,349 --> 00:45:49,025

And this is an industry where a lot of time employees coming out of universities and they're trained by people who never worked in the industry.

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00:45:49,344 --> 00:45:51,105

They don't understand the problem.

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00:45:51,105 --> 00:45:56,710

So it's very hard for them to actually train on how to solve some of the problems.

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00:45:57,030 --> 00:46:07,030

So for me, the training aspects that I received during residency, that instead of trained in a classroom by people who never did surgery,

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00:46:07,715 --> 00:46:17,235

trained in a surgical suite by surgeons, why I am assisting and helping with surgery is actually, I think, a very critical thing.

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00:46:17,235 --> 00:46:27,430

And here in this industry, we're making medications and things like insulin gene therapy that goes from \$05,000,000 to 5,000,000 a dose.

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00:46:28,390 --> 00:46:34,710

And yet people are trained in classroom by faculty who potentially never did this.

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00:46:35,030 --> 00:46:45,134

So I think changing the training and put them into a situation where they can learn by working with experts and all

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00:46:45,134 --> 00:46:53,179

of our faculty are coming from industry, I think, make a difference of what kind of workforce we develop for the future.

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00:46:53,179 --> 00:47:03,355

So I would like to see that students who graduate from university, even with PhDs, come and work in this kind of environment for

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00:47:03,355 --> 00:47:13,675

six months a year as part of their rotation because I think the translation and the CMC part of this new discovery is going to actually change

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00:47:13,675 --> 00:47:19,730

if we can incorporate something into as I said, even into the scientist training.

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00:47:19,730 --> 00:47:24,130

So they understand that how that idea can become a product.

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00:47:24,130 --> 00:47:25,809

And I think there's a huge gap there.

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00:47:25,809 --> 00:47:37,355

So these are the things that we would like to feel and be more like the, not the university, but the residency space for the workforce?

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00:47:37,914 --> 00:47:39,914

Well, thank you very much.

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00:47:40,394 --> 00:47:50,599

In summary, we've heard today about Open Biopharma, which focuses on operator and technician training

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00:47:50,840 --> 00:47:55,559

for pharmaceutical laboratories and manufacturing operations.

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00:47:56,440 --> 00:48:02,855

And you also do special projects, with a GMP facility.

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00:48:03,175 --> 00:48:11,815

So you're quite the resource, located North Of San Diego, but, you've you've got clients from across the country.

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00:48:12,295 --> 00:48:16,680

So I'd like to thank Susan and Richard for their time with us today.

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00:48:17,239 --> 00:48:24,920

It is great to hear about nonprofit efforts to train the pharmaceutical manufacturing and support personnel of the future.

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00:48:25,594 --> 00:48:32,315

That brings us to the end of another episode of the ISPE podcast, shaping the future of pharma.

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00:48:32,635 --> 00:48:41,559

Please be sure to subscribe so you don't miss future conversations with the innovators, experts and change makers driving our industry forward.

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00:48:42,119 --> 00:48:52,420

On behalf of all of us at ISPE, thank you for listening, and we'll see you next time as we continue to explore the ideas, trends and people shaping the

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00:48:52,420 --> 00:48:53,620

future of pharma.